UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

UNITED STATES OF AMERICA and STATE OF INDIANA ex rel. JUDITH ROBINSON, Plaintiffs, v. INDIANA UNIVERSITY HEALTH, INC., and HEALTHNET, INC., Defendants.	)	Case No. 1:13-cv-2009-TWP-MJD

RELATOR'S RESPONSE IN OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS RELATOR'S SECOND AMENDED COMPLAINT

COMES NOW Relator Dr. Judith Robinson and hereby opposes Defendants Indiana University Health, Inc. ("IU Health") and HealthNet, Inc.'s ("HealthNet") Motions to Dismiss. Dkts. 176 and 179, respectively.[1] This Court previously asked Relator to provide "examples with specific details where IU Health received an illegal kickback from HealthNet and *vice versa*" in order to provide "a sufficient level of detail regarding instances of kickbacks that violated the FCA and IFCA." Dkt. 153 at 25. Relator has done exactly that in her Second Amended Complaint, detailing four specific examples of kickbacks that IU Health paid to HealthNet in exchange for referrals of HealthNet's vast Medicaid patient population. As detailed herein, Relator has alleged violations upon which she, the United States, and the State of Indiana can be granted the relief sought in Relator's Second Amended Complaint. As is clear from their

[1] HealthNet offers no independent arguments in its Motion or associated Brief in Support (Dkt. 180), but rather incorporates IU Health's arguments in their entirety. Thus, for the sake of judicial economy, Relator responds to both Motions to Dismiss at one time, and will refer to all arguments as though made in full by both Defendants.

motions, Defendants are fully informed of the allegations against them so as to adequately prepare their defenses.

The root of Relator's kickback allegations is simple: IU Health offered and HealthNet accepted remuneration for sending HealthNet's Medicaid patients to Methodist Hospital for inpatient and ancillary services. As the Director of Women's Services at HealthNet *and* the Director of Ob/Gyn Services at Methodist Hospital, Relator Dr. Judith Robinson was in a unique position to gain personal knowledge of the allegations in her Second Amended Complaint. As Relator has alleged, the type and amount of remuneration varied for the different clinics and service lines – $1 per year leases on valuable commercial space, millions of dollars in subsidies, plus millions of dollars more directly tied to the number of patients referred by HealthNet to Methodist Hospital. But, the impact was the same for each scheme: IU Health offered and HealthNet accepted illegal kickbacks which rendered every claim for payment for the resulting referrals false and ineligible for reimbursement pursuant to the Anti-Kickback Statute ("AKS") and the federal and state False Claims Acts.

Defendants raise three distinct arguments in an effort to escape liability for these kickback schemes: (1) the Second Amended Complaint ("SAC") fails to satisfy Rule 9(b); (2) the SAC does not plausibly allege improper referrals, and (3) the arrangements are excepted from the Anti-Kickback Statute. Each of Defendants' arguments fails in light of the case law of the Seventh Circuit, the primary purpose of the Anti-Kickback Statute and the facts of the instant case. Defendants' selective analysis allows them to evaluate the SAC and relevant statutes in a vacuum, and to create their own standards to absolve them of any wrongdoing. Throughout their motions, Defendants offer arguments without legal support, disregard applicable case law, ignore the stated intent of Congress, cast aside regulations that do not comport with their position, and

overlook portions of the Second Amended Complaint entirely. Despite Defendants' contentions, Relator's Second Amended Complaint has provided detailed information regarding the kickbacks that were paid by IU Health to HealthNet in exchange for the referral of HealthNet's Medicaid patients in a manner that is consistent with the Seventh Circuit's pleading requirements, as well as the purpose and intent of the False Claims Act and the Anti-Kickback Statute.

For the reasons set forth herein, Relator respectfully requests that this Court deny Defendants' Motions to Dismiss Relator's Second Amended Complaint.

I. The Seventh Circuit's Rule 9(b) Standard for Anti-Kickback Cases Does Not Demand Individual Claims-Level Detail.

Defendants argue that Federal Rule of Civil Procedure 9(b) requires pleading "individualized transaction level" claims resulting from the kickback scheme. Dkt. 177 at 9-14. Rule 9(b) *does not* require the claims-level details that Defendants demand in their efforts to dismiss Relator's case. The plain language of Rule 9(b) does not require it, well-established Seventh Circuit case law does not require it, and even the cases from around the country upon which Defendants rely do not require it. In the instant case, the Court previously determined that Relator needed to include "examples with specific details where IU Health received an illegal kickback from HealthNet and *vice versa*" to satisfy the "sufficient level of detail regarding instances of kickbacks that violated the FCA and IFCA" required by Rule 9(b). Dkt. 153 at 25. Relator has provided those details, and more, in her Second Amended Complaint. Notably, the Court could have, and did not, ask for examples of illegal kickbacks *and the claims submitted as a result of those kickbacks*. That is because the law does not demand as much.

"Rule 9(b) requires that the plaintiff allege specific activity which constitutes the fraud so that the defendant may file an effective responsive pleading.... This is all Rule 9(b) requires."

U.S. ex rel. Gear v. Emergency Med. Assocs. of Ill., Inc., No. 00 C 1046, 2004 WL 1433601, at *6 (N.D. Ill. June 25, 2004). Defendants disregard the plain language of Rule 9(b) which requires only that a fraud-based complaint "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. Rule 9(b). The Rule does not demand nor address the need for specific claims resulting from the fraud; it requires the "circumstances constituting fraud" itself. The Seventh Circuit and its district courts have time and again emphasized the flexible nature of this standard. *U.S. ex rel. Schramm v. Fox Valley Physical Services, S.C. et al. ("Schramm II")*, No. 12 C 8262, 2016 WL 537951, at *2 (N.D. Ill. Feb. 11, 2016), *citing U.S. ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 853-54 (7th Cir. 2015); *Goldberg v. Rush Univ. Med. Ctr.*, 929 F. Supp. 2d 807, 821-22 (N.D. Ill. Mar. 6, 2013)(collecting cases).

While the Seventh Circuit has described Rule 9(b) as requiring the "who, what, when, where, and how: the first paragraph of any newspaper story," it has also admonished courts and litigants who "often erroneously take an overly rigid view of the formulation." *DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990); *Pirelli Armstrong Tire Corp. Retiree Med. Benefits Trust v. Walgreen Co.*, 631 F.3d 436, 442 (7th Cir. 2011). This Circuit has clarified that, "the requisite information – what gets included in that first paragraph – may vary on the facts of a given case." *Id.*; *AnchorBank, FSB v. Holder*, 649 F.3d 610, 615 (7th Cir. 2011)("[T]he exact level of particularity that is required will necessarily differ based on the facts of the case.") Rather than requiring a specific check-list of information, Rule 9(b) is satisfied so long as Relator's complaint shows, "in detail, the nature of the charge, so that vague and unsubstantiated accusations of fraud do not lead to costly discovery and public obloquy." *Lusby*, 570 F.3d at 854-55 ("Lusby's accusations are not vague. Rolls-Royce has been told exactly what the fraud entails."); *Goldberg*, 929 F.Supp.2d at 822 (denying a motion to dismiss where the complaint

gave "[d]efendants sufficient notice to prepare a defense against the claim. Relators' allegations do not vaguely refer to unidentifiable transactions and misrepresentations.").

Defendants rely on the district court *Lusby* opinion for the proposition that "'actual claims must be specifically identified' in an FCA relator's complaint." Dkt. 177 at 10, *citing U.S. ex rel. Lusby v. Rolls-Royce Corp.*, No., 1:03-CV-0680-SEB/WTL, 2007 WL 4557773, at *5 (S.D. Ind. Dec. 20, 2007). This mischaracterizes the *Lusby* holding. The Seventh Circuit explained: "True, it is essential to show a false statement. But much knowledge is inferential." Thus, rather than creating a strict pleading requirement, "[t]he court's decision [in *Lusby*] suggests, however, that it would apply a flexible approach." *U.S. ex rel. Schramm v. Fox Valley Physical Servcs., S.C. ("Schramm I")*, No. 12 C 8262, 2015 WL 3862954, at *3 (N.D. Ill. June 22, 2015)(quoting *Lusby* for the proposition that, "We don't think it essential for a relator to produce the invoices (and accompanying representations) at the outset of the suit."). This is consistent with a pleading standard "that effectuates Rule 9(b) without stymieing legitimate efforts to expose fraud" by allowing that "a relator's complaint, if it cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)(applying a similarly flexible Rule 9(b) standard); *accord Goldberg*, 929 F.Supp.2d at 818.

There are undoubtedly cases which require claims-level detail in order to identify the "circumstances constituting fraud," – circumstances where a claim would be false *only* because of what was written on the face of the claim itself, such as up-coding or billing for services not rendered. *See, e.g., U.S. ex rel. Coots v. Reid Hosp. & Health Care Servs., Inc.*, No. 1:10-cv-0526-JMS-TAB, 2012 WL 3949532, at *1 (evaluating seven billing practices where falsity was

on the face of the claim); *U.S. ex rel. Fowler v. Caremark RX, L.L.C.*, 496 F.3d 730, 741-42 (7th Cir. 2007), *overruled on other grounds, Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907 (7th Cir. 2009)(evaluating double-billing which would only be evident on the face of claims). These sorts of cases give rise to Defendant's oft-repeated demand for details "at an individualized transaction level." See Dkt. 177 at 10, 11, 12 and 14, citing *Fowler*, 496 F.3d at 741-42. However, this is not a universal maxim. *Schramm II*, No. 12 C 8262, 2016 WL 537951, at *7 ("[Defendants] cite the Seventh Circuit's requirement in *Fowler* of 'evidence *at an individualized transaction level*' to sustain an FCA claim. But the scheme alleged in *Fowler* was so different from the scheme alleged here that it renders the Seventh Circuit's holding inapplicable"). Rather, that Relator does not "attach an actual claim submitted to [the Government] or proof-of-payment received by defendants is of no moment [where] she has plausibly alleged a scheme to defraud the government and the defendants are adequately on notice of the false claims and misconduct alleged." *Id*.

Anti-kickback cases do not fall into the category of cases where circumstances which cause a claim to be false would be visible on the face of claims themselves. Defendants present three cases in addition to *Fowler* as purported examples of anti-kickback cases which were dismissed for failure to plead with specificity. Dkt. 177 at 12, 14. Yet, even those cases *support*, rather than refute, the proposition that the "circumstances constituting fraud" in an anti-kickback case are those related to the *kickback scheme*, not the resulting claims submitted to the Government. *See also U.S. ex rel. Kroening v. Forest Phara., Inc.*, No. 12-CV-366, 2016 WL 75066, at *6 (E.D. Wisc. Jan. 6, 2016)("[I]n light of the mutual purpose of the Anti-Kickback Statute and the FCA in preventing fraud against the government and the necessity of complying with the Anti-Kickback Statute for payment under the relevant government programs, it logically

follows that, when a violation of the Anti-Kickback Statute leads to a claim submitted to the government that it would not have paid had it known of the violation of the Anti-Kickback Statute, such a claim is false and actionable under the FCA.")

For example, in *U.S. ex rel. Grandeau v. Cancer Treatment Ctrs. of Am.*, the Northern District of Illinois dismissed four hyper-broad paragraphs making up an AKS allegation between individual doctors and a paying entity because the relator "fail[ed] to name specifically any physician who made referrals prohibited by the Stark Act, or any other person who solicited, received, offered, or paid any remuneration in exchange for the referral of a patient, [nor] any dates, or a general time frame, when the alleged wrongdoing occurred." No. 99 C 8287, 2005 WL 2035567, at *2 (N.D. Ill. Aug. 19, 2005). The *Grandeau* opinion also refers to "representative examples to illustrate the alleged *unlawful activity*" as opposed to the resulting claims. *Id*. (Emphasis added.) Likewise, in *U.S. ex rel. Obert-Hong v. Advocate Health Care*, the court dismissed a complaint pleading violations of the Stark and AKS laws because "the complaint says little about the acquisition transactions." 211 F.Supp.2d 1045, 1049 (N.D. Ill. Jan. 30, 2002). There, the court determined the complaint was "not sufficient to plead fraud" because it "[did] not identify what assets were purchased, the amounts paid, or anything beyond conclusory allegations that they were not commercially reasonable." *Id.* Like *Grandeau*, the *Obert-Hong* court focused only on the need for specifics regarding the *kickbacks* that were paid and received, and made no mention of claims for payment to the Government. Finally, Defendants find no more support in *U.S. ex rel. Grenadyor v. Ukranian Vill. Pharmacy, Inc.*, 895 F.Supp.2d 872, 879 (N.D. Ill. Sept. 5, 2012). There again, the court faulted relator for failing to plead the "who, what, where, when, and how" of the *kickback itself*. *Id.* at 878-890 (noting the Relator came close to satisfying Rule 9(b) for one scheme, but left out the "who" – who gave the

kickbacks or at least directed that they be given). But, the court expressly disagreed with the need for a specific claim to the Government. *Id*. Once again, the court invoked *Lusby* in finding "while this could be an impediment in some cases...this is not necessarily true if sufficient other detail is pled." *Id.* at 879-80.[2]

Finally, Relator has pled – and Defendants don't dispute – that both IU Health and HealthNet are Medicaid providers, and that the majority of HealthNet patients are Medicaid recipients. SAC at ¶¶1, 18 (62% of HealthNet's total patient population receives Medicaid). Indeed, at no time have Defendants disputed that they submitted, or caused to be submitted, claims to the Government. Thus, it is not just plausible that Defendants submitted false claims to the Government based on the schemes that Relator has alleged, but utterly implausible that they did not. *Lusby*, 570 F.3d at 854-55; *U.S. ex rel. Geschrey v. Generations Healthcare, LLC*, 922 F.Supp.2d 695, 705 (N.D. Ill. Aug. 14, 2012)(evaluating Seventh Circuit law and intent in determining "the fact that most of Generation's patients were receiving government benefits and Generations billed Medicare and Medicaid at a *per diem* rate for each covered patient creates a strong inference that bills for the care of patients as to whom fraud has been alleged were submitted to the Government"); *Grenadyor*, 895 F.Supp.2d at 880 ("[I]t would be reasonable to infer that Medicare and Medicaid were billed for these specific transactions; to infer otherwise would mean UV Pharmacy was filling thousands of prescriptions entirely out of its own pocket.").

[2] Defendants cite this case as being affirmed by the Seventh Circuit. It was not. A later ruling on the relator's third amended complaint (which Defendants do not cite) was reviewed and affirmed by the Seventh Circuit. No. 09 C 7891, 2013 WL 6009261 (N.D. Ill. Nov. 7, 2013), *aff'd by* 772 F.3d 1102 (7th Cir. 2014). Like the previously-discussed cases, the Seventh Circuit faulted Relator's complaint for failing the "who" requirement of the fraud scheme – a Medicare or Medicaid patient who received the kickback. 772 F.3d at 1107. That flaw made the details regarding the *payment of a kickback* incomplete, but still the Court did not seek details on the claims submitted to the Government. The other scheme evaluated by the Seventh Circuit involved non-AKS claims which would be false on their face – not analogous to the claims in the instant case. *Id.* at 1107-08.

Consequently, Rule 9(b) does not require "individualized transactions" at the claims level for the False Claims Act anti-kickback case alleged by Relator. As discussed in detail, *supra*, Relator pled ample details about the "who, what, where, when, and how" of the fraudulent schemes which induced the referral of HealthNet's vast Medicaid population to IU Health's Methodist Hospital – these are the "circumstances constituting fraud" required by Rule 9(b). Claims-level detail for the resulting false claims would not provide Defendants any additional notice about the fraud alleged against them nor put Defendants in a better position to defend themselves than they already are. Rather, Defendants' arguments would take the "big bite out of *qui tam* litigation" against which the Seventh Circuit protects. *Lusby*, 570 F.3d at 854.

A. Relator's Kickback Allegations Satisfy Rule 9(b).

Defendants do not argue that Relator failed to provide the requisite level of detail as to the kickback schemes. In fact, in six pages of arguments on Rule 9(b), Defendants never once say that they do not understand the nature of the allegations raised against them, that they are inadequately equipped to respond to the charges levied by Relator, or that the detail of Relator's complaint leaves open the possibility that the charges of kickback violations are spurious or unfounded.[3] This is because Relator pleads facts – and provides supporting documentation[4] – specifically identifying the arrangements at issue in this case, as well as details about the creation of each arrangement. And while Relator does identify the specific individuals responsible for formalizing each arrangement, the "who" for every arrangement are the entities themselves – IU Health paid the kickbacks and HealthNet received them. The kickbacks flow from entity to

[3] Defendants make passing references throughout their briefs alleging that (1) Relator's claims are brought as a result of information learned in discovery, *and* (2) Relator "ignored" information learned in discovery that would disprove her theories. Neither argument is true, nor appropriate at this stage of litigation.

[4] Unlike many other cases, Relator's complaint provides the exact contracts related to each specific arrangement, thus leaving Defendants with no possible uncertainty about which arrangements Relator has alleged to be fraudulent.

entity rather than to or from one specific doctor or patient, thus ensuring that *all* claims submitted by either Defendant as a result of these arrangements are tainted by the illegal schemes. *Kroening*, No. 12-CV-366, 2016 WL 75066 at *6. Accordingly, as described here, Relator has identified the "who, what, where, when, and how" of each of the four distinct kickback schemes in her Second Amended Complaint.[5]

Moreover, Relator explains how each scheme is an example of Defendants' overall goal of exploiting HealthNet's access to enhanced payments as a federally qualified health center ("FQHC") while still ensuring that patients would be referred to Methodist Hospital for labor, delivery, newborn and child care, and other ancillary services. See, e.g., SAC Exhibits I and J (IU Health transferring the PACC to HealthNet for $1 because "[T]he Parties believe that HealthNet, as a federally qualified health center (FQHC), will be eligible for improved reimbursement from the operation of the PACC..." then providing free rent, but putting an exclusive referral clause into the lease); [redacted] It is this collective pattern of illegal arrangements that gives rise to Counts I and II of Relator's complaint. SAC ¶¶96; 102 ("Defendants have knowingly and willfully offered and accepted remuneration, and entered into multiple financial compensation arrangements which were created with the purpose of inducing referrals from Defendant HealthNet to Defendant IU Health's Methodist Hospital. This conduct is in direct violation of the Anti-Kickback Statute."). Thus, while Relator has pled details for each individual scheme, Counts I and II should not be dismissed even if the Court determines that any one part does not satisfy Rule 9(b), because Relator has still

[5] The facts alleged in Relator's Second Amended Complaint, which will be proven in detail as the case progresses, enjoy the presumption of truth at this phase of the Court's evaluation. *Bielanski v. County of Kane*, 550 F.3d 632, 633 (7th Cir. 2008).

provided information sufficient to put Defendants on notice that their conduct, taken as a whole, violated the Anti-Kickback Statute.

The relationships between IU Health[6] and HealthNet stem from a 1999 Affiliation Agreement that was created ostensibly to formalize how the entities would work together to provide "the staff and expertise to manage and serve the needs of [HealthNet's] community health centers." SAC ¶43; Exhibit A at 2. The Affiliation Agreement was expressly portrayed as "a full statement of [the Parties'] agreement in connection with [IU Health]'s and HealthNet's desires to coordinate their efforts to achieve their mutual missions to improve community health." Exhibit A at 3. In that Agreement, IU Health agreed to fund [redacted] Historical Line of Credit to be repaid "as HealthNet's overall financial condition permits...." SAC ¶44; Exhibit A at 9. The Agreement does not contemplate any increase in the Historical Line of Credit. SAC ¶44. Yet fifteen years later, in the wake of multiple arrangements between IU Health and HealthNet and with no amendments to the Affiliation Agreement, the initial million-dollar loan has ballooned into a $13,797,563 unpaid debt – with no sign of repayment, past or future. SAC ¶45; Exhibit B. HealthNet's *carte blanche* access to the Bank of IU Health paved the way for the following four arrangements, some of which were at least crafted to appear reasonable but which are actually blatant kickbacks when viewed in light of the [redacted] increase in interest-free, unpaid debt owed by HealthNet to IU Health.

Hospitalist Agreement

Relator sets forth the "who, what, where and when" of the Hospitalist Agreement in straightforward fashion: the deal was formalized by HealthNet's CEO Booker Thomas ("Thomas") and IU Health Methodist Hospital's CEO Sam Odle ("Odle") in October 2005 in an

[6] IU Health was formerly named Clarian Health Partners, Inc. and changed its name to Indiana University Health, Inc. effective April 1, 2011. For purposes of clarity, Relator refers to the entity as "IU Health" throughout this brief.

effort to avert Methodist Hospital's anticipated loss of 1,500 deliveries per year to competitor hospitals. SAC ¶¶47-48; Exhibit C. The "how" of the arrangement is also simple: IU Health paid remuneration to HealthNet to ensure HealthNet's pregnant patients (and ultimately their newborns) were treated at IU Health's Methodist Hospital. As Relator alleges, Defendants put into place a Hospitalist Agreement which provided for IU Health to pay HealthNet $1,200,000 for physician coverage, plus the cost of 2.5 full-time equivalents for CNM coverage, and a small portion of the physicians' medical malpractice insurance in exchange for HealthNet staffing Methodist Hospital's Labor and Delivery floor and its associated triage unit. SAC ¶48; Exhibit C. Dr. Marshall Keltner ("Keltner"), acting on HealthNet's behalf, renegotiated part of the Agreement in September 2008 to increase the funding to $1,500,000 with annual increases plus the *full* cost of the providers' malpractice insurance; this amendment was executed by Thomas on behalf of HealthNet and John Kohne on behalf of Methodist Hospital. SAC ¶48; Exhibit D.

IU Health funneled money to HealthNet by assigning to HealthNet all professional billings for Ob/Gyn and advanced practitioner services provided in Methodist Hospital's L&D and triage units. SAC ¶48; Exhibit C at 4. The assigned billings were uncapped, and thus had no relationship to HealthNet's actual expenses. SAC ¶48. Rather, the value of the arrangement to HealthNet directly depended on the number of patients it referred to Methodist Hospital: HealthNet made money on every patient who received treatment in Methodist Hospital's labor and delivery unit that it would not have made if the patient was directed to another hospital. *Id*. In FY 2012-2013, HealthNet's patients accounted for 2,422 deliveries at Methodist Hospital. SAC ¶18. The relationship was also financially beneficial to IU Health. Relator alleges that IU Health billed for ancillary services, tests, and procedures, as well as more than $40 million per year for the care of newborns born at Methodist Hospital as a result of this kickback

arrangement. SAC ¶49. Relator also alleges the arrangement resulted in increased Disproportionate Share Hospital funds allocated to IU Health as a result of the additional admissions. *Id*.

Every patient identified as a bad outcome or "near miss" by Relator was referred by HealthNet to Methodist Hospital as a result of the Hospitalist Arrangement. SAC ¶¶84(a)-(g), 87. Despite their insistence that claims-level data is needed, Defendants apparently did not recognize examples of the resulting claims when provided. This failure to connect the patients to the AKS scheme illustrates the reason individualized transactions are not necessary in this type of case; listing more of the same would in no way enhance Defendants' ability to understand or defend against the fraud alleged against them.

Maternal-Fetal Medicine

The "who, what, where, when, and how" of Relator's allegations related to the development of the maternal-fetal medicine ("MFM") clinic not only describe the illegal kickbacks, but also the intentions and negotiations leading up to the arrangement. As alleged, the concept of developing a new method to funnel the highest-risk pregnant patients to Methodist Hospital was the result of a decrease in maternal-fetal medicine patient volume in the mid-2000's combined with HealthNet's desire to develop a new revenue stream. SAC ¶¶50, 51. Sensing opportunity, teams from both IU Health and HealthNet engaged in discussions about "MFM at Methodist Hospital" starting around November 2008. SAC ¶51; Exhibit E. The conversations – led by HealthNet's CMO Don Trainor and including Methodist Hospital's COO John Kohne and Dr. Keltner (this time wearing his "Director Ob/Gyn Services, Methodist Hospital" cap) – had a clearly expressed goal: "reinstitute a more robust outpatient and inpatient MFM presence on the Methodist Hospital campus." SAC ¶¶51-52; Exhibit E; *see also* Exhibit F at 1 ("[IU Health]

desires to expand access to Maternal-Fetal Medicine Services at Methodist Hospital..."). Relator's allegations indicate that HealthNet did not *need* to be part of any plan to bring MFM services to Methodist Hospital – IU Health owned the commercial building where the clinic was ultimately located (SAC ¶56; Exhibit H); an IU Health-affiliated entity (University Obstetricians-Gynecologists, Inc. or "UOG") would be paid to provide the physician services (Exhibit F at 1); and IU Health would be fully shouldering any expenses or losses associated with the program so HealthNet would be financially risk-free (SAC ¶54; Exhibit F at 1-2). But Trainor's email betrayed the true reason HealthNet was being pulled into the mix: "[W]e would work to redirect MFM business back to Methodist Hospital from other delivery systems...." Exhibit E at 2. Simply, HealthNet was looking for a way to make money, and IU Health needed HealthNet's patients to make its reestablished MFM program lucrative. SAC ¶¶51, 52.

Relator's allegations and supporting documents leave no doubt that the arrangement was created to funnel HealthNet patients to Methodist Hospital. [redacted] Apparently satisfied with the return on investment resulting from "increased volume of procedures, surgeries and NICU stays at Methodist" that Trainor contemplated, IU Health and HealthNet entered into a series of agreements to create and staff HealthNet's new Maternal-Fetal Medicine Clinic in 2010. SAC ¶¶54, 56, 57; Exhibits E and F. The Parties entered into a lease agreement for Suite 486 of IU Health's medical building located at 1633 North Capitol, Indianapolis, IN, which was ostensibly "commercially reasonable and consistent with fair market value." Exhibit F at 2; Exhibit H. But, the arrangement was pure smoke-and-mirrors because HealthNet never paid rent on the space and never intended to do so.

SAC ¶56, *see also* SAC ¶45 (increasing, unpaid, interest-free debt). Thus, formalizing the lease had only one practical purpose – to force HealthNet into signing the exclusive referral agreement attached to the lease. Exhibit H at 18 (requiring that "[IU Health] will continue to provide all ancillary services and outpatient procedures such as radiology, ultrasound, laboratory, anesthesia, cardiovascular, neurological, physical therapy, vascular and other services, tests and procedures other than those provided by the Physician Occupants in his/her own office for his/her own patients.")

IU Health also enabled HealthNet to collect the professional fees for each MFM patient referred to Methodist Hospital from the new MFM clinic. SAC ¶54. Therefore, as with the Hospitalist Agreement, HealthNet received money for every MFM patient that it sent to Methodist Hospital which it would not have received if the patient had gone to any other hospital. *Id*. Relator alleges that IU Health received the exact benefit it had anticipated – increased referrals of MFM patients resulting in admissions of HealthNet's sickest babies to Methodist Hospital's NICU. SAC at ¶¶55, 58.

[redacted] Dr. Robinson observed that the MFM clinic was busier than had been expected. In 2011, Relator alleges that MFM specialist Dr. Men-Jean Lee told Dr. Robinson that HealthNet needed more staff and more equipment to keep up with volume. SAC ¶57. IU Health approved a request from HealthNet COO Elvin Plank to expand the services in August 2011. *Id*. The expanded services increased the resulting NICU admissions, as well. SAC ¶58. Dr. Robinson personally observed Methodist's NICU patient census increase from approximately 8-10 babies to rarely less than 20-25 babies at any given time. *Id*.

Pediatric and Adolescent Care Clinic

The allegations describing the free transfer of the Pediatric and Adolescent Care Clinic ("PACC") from IU Health to HealthNet also describe the "who, what, where, when, and how" of the kickback scheme. Relator alleges that Booker Thomas and Don Trainor explained that in late 2008, IU Health gave HealthNet the PACC clinic for free in exchange for all referrals for in-patient care, specialty care, and ancillary services flowing from PACC patients. SAC ¶59. The documents describe that the exact arrangement outlined to Dr. Robinson – the PACC was transferred by IU Health to HealthNet at no cost in October 2008 by Sam Odle for Methodist Hospital/IU Health and Booker Thomas for HealthNet. Exhibit I. In 2010, when a lease was finally signed by then-COO Elvin Plank for HealthNet and Mark Bode for IU Health (it was backdated to be effective from the time of the transfer), the Defendants memorialized their agreement that IU Health would charge HealthNet $1 per year for "rent" and that HealthNet would use IU Health as its exclusive provider for ancillary services. Exhibit J at 1, 2, 15. The entities doubled-down on their arrangement in 2012 when IU Health funded a massive expansion in clinic space, yet still did not increase the $1 per year rent. SAC ¶59(b).

Like all the other arrangements, Defendants do not argue that Relator has not identified the "who, what, where, when and how" of the PACC scheme. Rather, the only defect Defendants attempt to assign to the PACC kickback scheme is that "Relator alleges only the *possibility* of improper referrals." MTD at 12 (quoting SAC ¶59(a)). Defendants read this allegation in a vacuum. True, Relator *does* allege that "IU Health expected all referrals for in-patient care, tests, procedures, specialist referrals or other ancillary services flowing from PACC to be directed to Methodist Hospital." SAC at ¶59(a). This statement clearly speaks to IU Health's intent to induce referrals by giving HealthNet the PACC clinic for free and charging $1

per year rent for the commercial space. The rest of the allegations, however, indicate that IU Health's intent was not just carried out (Exhibits I and J), but that the arrangement was so successful that IU Health was willing to increase the space it gave to HealthNet for the PACC clinic and *still* not charge HealthNet for the clinic or the additional space. SAC ¶¶59(b)-(c).

Avondale

Relator's allegations regarding the development of the Avondale Meadows Health Center (now called the "Northeast Health Center") also identify the "who, what, where, when and how" of IU Health's development and funding of a new HealthNet clinic in exchange for HealthNet's referral of its expanded patient base. In June 2012, IU Health and HealthNet signed an agreement (again by Thomas and Odle) wherein IU Health would fund the development of a community center to contain a new HealthNet clinic. Exhibit K. Just like with the MFM clinic, IU Health agreed to pay HealthNet's lease obligations for the clinic location as well as any losses associated with the operation of the clinic. *Id*. at 2, 3.

This time, however, the unlimited funding came with unique conditions attached. *Id.* at 3. IU Health structured the arrangement so that it was only obligated to continue covering HealthNet's losses *unless* "IU Health, *in its sole discretion*, believes that HealthNet, after discussion with IU Health has not taken appropriate steps to mitigate [losses]." *Id.* (Emphasis added.) The terms of IU Health's support also required that HealthNet engage in "ongoing collaborative discussions regarding HealthNet/Meadows Operations with IUH." *Id.* IU Health's list of suggested "discussion topics" included "best practices and enhanced integration between the parties related to clinical, operational, and financial planning at HealthNet's Avondale-Meadows community health center" – topics that dispel any suggestion of an arms' length transaction. *Id*. Thus, HealthNet had "nothing to lose" *only if* it satisfied IU Health's

expectations for operations of the clinic. SAC at ¶ 59(e). Thus, as Relator pled, the conditional remuneration was put into place to ensure that HealthNet was incentivized to refer all its new Avondale patients to IU Health. SAC at ¶59(f); Exhibit K.

As with the PACC clinic, Defendants raise the same flawed argument that Relator alleged "only the *possibility* of improper referrals" related to the Avondale clinic. MTD at 12. Yet, like PACC (and the other arrangements), Relator has pled more than sufficient details and identified specific documents to show that these were not just plans or intentions which were left unfinished. The Avondale plan was executed, and patients were treated and referred accordingly. SAC ¶59(f), Exhibit K. Thus, while Defendants' cherry-picked comments *do* speak to IU Health and HealthNet's *intent* to induce referrals during the planning of these relationships, the executed agreements and the conduct as a result of the agreements speak to the fact that the intent was fully effectuated.

II. Referrals Occurred as a Result of the Kickback Scheme.

Defendants' argument that Relator failed to state a claim because HealthNet, as opposed to the individual physicians, received remuneration from IU Health fails both as a matter of law and as applied to the facts of this case. Defendants raise two arguments here: (1) that only a physician who refers can receive an illegal kickback, and (2) if an entity receives the kickback, it must "unduly influence" the physicians referrals to violate the AKS. Dkt. 177 at 14-15. Defendants' first argument leads to an "absurd" result which the Seventh Circuit has repeatedly rejected. Their second argument disregards the complete control HealthNet held over referrals from its clinics.

Defendants first argue that the AKS only criminalizes the payment of kickbacks to referring physicians, specifically stating that "the person receiving remuneration must be the

same person referring patients." Dkt. 177 at 15. Defendants do not – and cannot – cite to any authority in support of this assertion. In fact, relevant case law directly refutes it. This interpretation is directly at odds with the definition of "person" supplied by the applicable statute. Per 42 U.S.C. §1301(a)(3), the term "person" as used in that chapter means "an individual, trust or estate, a partnership, or a corporation." Defendants' interpretation would limit "person" to only an individual, thus violating "the cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant." *U.S. ex rel. Garbe v. Kmart Corp.*, --- F.3d ---, No. 15-1502, 2016 WL 3031099, at *5 (7th Cir. 2016), *citing TRW Inc. v Andrews*, 534 U.S. 19, 31 (2001). Moreover, the Seventh Circuit has twice rejected this exact proposition. *U.S. v. Polin*, 194 F.3d 863 ("To adopt this view would lead to absurd results. Only a physician could violate Subsection A as only he can 'refer' a patient. ... This is clearly a perversion of the Act and we decline to read it that way."); *U.S. v. Patel*, 17 F. Supp. 3d 814, 827 (N.D. Ill. 2014), *aff'd*, 778 F.3d 607 (7th Cir. 2015)("Narrowly construing the term 'referring' to mean only 'personally directing a patient to a particular entity' is at odds with the broad nature of the statute.").

Defendants ultimately concede that the AKS *does* apply to non-referring entities, but argue that Relator has not alleged that "HealthNet controls or constrains doctors' referral decisions in any way." Dkt. 177 at 15. This ignores the weight of the allegations in Relator's complaint which establish that as a result of the agreements and arrangements between Defendants, HealthNet providers referred patients to IU Health's Methodist Hospital. Perhaps most tellingly, HealthNet's CMO Don Trainor himself stated that referrals would result from the proposed relationship between IU Health and HealthNet. SAC Exhibit E (Trainor wrote that

HealthNet "would work to redirect MFM business back to Methodist Hospital from other delivery systems..." and that the team was working "to get a feeling for the volume of MFM referrals that could be redirected to Methodist as well as some financial numbers around increased volume of procedures, surgeries and NICU stays at Methodist from such redirection.").

[redacted] IU Health knew that entering into agreements with HealthNet would guarantee referrals to Methodist Hospital.

Moreover, Relator's complaint makes clear that HealthNet *did* have policies directing the referrals of HealthNet patients to IU Health's Methodist Hospital.[7] HealthNet's website provided patients with responses to "Frequently Asked Questions" including "Where will I give birth?" SAC ¶64. HealthNet could have responded with "You may give birth wherever you choose" or "Your physician will direct you to the most appropriate hospital," but it did not. Instead, HealthNet published this response: "Births are attended by the HealthNet nurse-midwives *at Methodist Hospital*." *Id*. (Emphasis added.) Relator also quoted a 2012 email from Mickki Ashworth, the Clinic Manager for HealthNet's largest clinic location, wherein Ashworth explained that referral decisions were directly related to the arrangements between IU Health and HealthNet. SAC ¶46. Ashworth wrote, "We have a business relationship and partnership with IU Health. All of our patients deliver at Methodist and are sent to Methodist because that is part of our partnership." *Id.*

[7] Defendants acknowledge that Relator identified HealthNet's policy that providers enter every HealthNet patient's medical information into IU Health's computer system. Dkt. 177 at 16; SAC ¶75. Contrary to Defendants' argument, this policy supports Relator's allegations that HealthNet influenced and directed physicians' referrals. Forcing a provider to put patient information into the electronic records of one hospital indisputably influences where that patient will receive hospital-based services.

Therefore, it is apparent from Relator's allegations the agreements and arrangements entered into by HealthNet caused the referrals of HealthNet patients to Methodist Hospital. *See Patel*, 17 F. Supp. 3d at 827 ("Unlike the defendant in *United States v. Miles*, Defendant was a 'relevant decisionmaker'" in directing where referrals were sent.)(citation omitted). As Relator has alleged, IU Health was willing and did pay HealthNet remuneration in exchange for securing the referral of HealthNet's vast supply of Medicaid patients to Methodist Hospital. This sort of scheme "squarely falls within the meaning and plain language of the Act." *Polin*, 194 F.3d at 867.

III. Defendants' Conduct is Not Protected by the Nine-Part Standard for the Statutory Exception related to Federally Qualified Health Centers.

In their final argument, Defendants contend that three of the kickback violations in Relator's complaint are protected by a statutory exception to the AKS.[8] Defendants fail to identify that the statutory exception is applied through a nine-part test set forth in the health center safe harbor. 42 C.F.R. § 1001.952(w). Defendants concede that the safe harbor does not apply on the face of Relator's allegations. Dkt. 177 at 18, n.4. Here, Relator and Defendants agree. Because it is abundantly clear from the face of Relator's allegations that the safe harbor does not apply (and because Defendants have waived the argument by conceding the point), there is no basis to dismiss Relator's Second Amended Complaint. *U.S. v. Rogan*, 459 F.Supp.2d 692, 716 (N.D. Ill. Sept. 29, 2006), *aff'd* 517 F.3d 449 (7th Cir. 2008)(protection of a safe harbor is an affirmative defense that Defendant bears the burden of establishing); *Levin v Miller*, 763 F.3d 667, 671 (7th Cir. 2014)(complaints need not anticipate affirmative defenses).

Rather than the appropriate nine-part test, Defendants craft a three-part test which evaluates the statutory language in a vacuum, and then argue that their self-created test

[8] Defendants fail to explain why the fourth arrangement, the Hospitalist Agreement, wouldn't fall into this same flawed argument.

necessitates the dismissal of Relator's allegations. However, Defendants' proposed interpretation is devoid of any legal support and would apply to virtually any arrangement involving a federally qualified health center ("FQHC") in direct contravention to Congress's intent. *F.T.C. v. IFC Credit Corp*., 543 F.Supp.2d 925, 934 (N.D. Ill. Apr. 9, 2008), citing *Chevron U.S. A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 844 (1984)("If Congress has made its intent clear, the court and agency must give Congress's intent effect."). "A reviewing court should not confine itself to examining a particular statutory provision in isolation," but rather "the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 666 (2007)(internal quotations omitted). In this case, the statutory exception related to FQHCs is expressly intended to be viewed in concert with the health center safe harbor.

Congress's intention to create leeway for some, but not all, arrangements regarding FQHCs is expressly stated in the enacting legislation - the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"). Pub. L. 108-173, § 431.[9] The MMA set forth the statutory language quoted by the Defendants in Section 431(a). *Id.* at § 431(a)(3). In the next paragraph of the MMA, Section 431(b), Congress mandated that "the Secretary [of Health and Human Services] shall establish, on an expedited basis, standards relating to the exception...." *Id.* at § 431(b)(1)(A). Congress went on to enumerate specific factors that must be considered in the rulemaking process and gave its consent for other "standards and criteria to be consistent with the intent of Congress in enacting the exception established under this section." *Id.* at § 431(b)(1)(B).

[9] The exception was originally codified as 42 U.S.C. 1320a-7b(b)(3)(H). It was redesignated as §1320a-7b(b)(3)(I) in 2010. Pub L. 111-148, § 3301(d)(1)(C)(i).

In response, the U.S. Department of Health and Human Services, Office of Inspector General ("HHS-OIG") issued a Notice of Proposed Rulemaking on July 1, 2005. The Notice expressly stated that, "[I]n accordance with section 431 of [MMA], Public Law 108-173, this proposed rule would establish regulatory standards for the new safe harbor under the Federal anti-kickback statute for certain [remuneration] provided by individuals and entities to certain health centers funded under section 330 of the Public Health Service Act." Notice of Proposed Rulemaking, 70 Fed. Reg. 38,081 (July 1, 2005). HHS-OIG also recognized that "Section 431 of MMA amends the anti-kickback statute to create a new safe harbor for certain agreements involving health centers." *Id.* at 38,083. The Notice discusses the MMA in detail:

> Section 431(b) of MMA requires the Department to promulgate regulatory standards relating to the new safe harbor. In establishing the standards, Congress directed the Department to consider the following factors:
>
> • Whether the arrangement results in savings of Federal grant funds or increased revenues to the health center. We believe this factor evidences Congress's intent that a protected arrangement directly benefit the health center economically and that the benefits of the arrangement primarily inure to the health center, rather than the individual or entity providing the remuneration.
>
> • Whether the arrangement restricts or limits patient freedom of choice. We believe this factor evidences Congress's intent that protected arrangements not result in inappropriate steering of patients. Under the safe harbor, patients remain free to obtain services from any provider or supplier willing to furnish them.
>
> • Whether the arrangement protects the independent medical judgment of health care professionals regarding medically appropriate treatment for patients. We believe this factor evidences Congress's intent to safeguard the integrity of medical decision-making and ensure it is untainted by direct or indirect financial interests. In all cases, the best interests of the patient should guide the medical decision-making of health centers and their affiliated health care professionals.
>
> Section 431(b)(1)(B) of MMA provides that these three factors are ''among'' the factors the Department may consider in establishing the safe

> harbor standards. The statute authorizes the Department to include ‘‘other standards and criteria that are consistent with the intent of Congress in enacting’’ the health center safe harbor. Section 431(b)(1) of MMA. Accordingly, we interpret the statute to permit us to consider other relevant factors and to establish other relevant safe harbor standards consistent with the anti-kickback statue and the health center exception. Among the factors we have considered is whether arrangements would pose a risk of fraud or abuse to any Federal health care programs or their beneficiaries. We believe Congress intended to protect arrangements that foster an important goal of the section 330 grant program — assuring the availability and quality of needed health care services for medically underserved populations — without adversely impacting other Federal programs or their beneficiaries.

Id. at 38,083.

The resulting safe harbor was codified at 42 C.F.R. § 1001.952(w); *see also* Final Rule, 72 Fed. Reg. 56,632 (Oct. 4, 2007). The "health center" safe harbor states that, "As used in section 1128B of the Act, 'remuneration' does not include the transfer of any goods, items, services, donations or loans (whether the donation or loan is in case or in-kind), or combination thereof from an individual or entity to a health center (as defined in this paragraph), *as long as the following nine standards are met*...." (Emphasis added.) Thus, the appropriate method to evaluate whether an arrangement involving an FQHC is outside the scope of the Anti-Kickback Statute is the nine-part test set forth in the "health center" safe harbor, not the three-part analysis concocted by Defendants.

As conceded by the Defendants, the arrangements between IU Health and HealthNet do not satisfy all nine elements of the safe harbor. For example, the safe harbor sets forth a requirement that remuneration be set forth as a fixed amount, fixed percent, or fixed formula. 42 C.F.R. §1001.952(w)(1). However, the [redacted] loan from IU Health to HealthNet was contracted to be a repayable [redacted] loan in 1999, but has ballooned to $13.7 million debt without any fixed formula, any specificity as to the goods or services it now covers, nor anything

beyond an "unlikely" chance of repayment. SAC ¶¶44-45, Exhibits A and B. Similarly, the safe harbor establishes that an FQHC not be required to refer patients to a particular entity and must notify its patients of a choice of providers. 42 C.F.R. §1001.952(w)(5)(i)-(ii) and (w)(8). As described in detail herein and throughout the Second Amended Complaint, IUH provided sweetheart deals and under-market loans and leases to HealthNet contingent upon HealthNet's commitment that its patients will be exclusively referred to Methodist Hospital; HealthNet satisfied the demand. SAC *passim*. These arrangements not only fail to satisfy the statutory exception or the regulatory safe harbor, but they are exactly the sort of arrangements that Congress has prohibited through the federal Anti-Kickback Statute. Consequently, the statutory exception relied upon by Defendants does not apply and cannot be a basis for dismissal.

IV. Conclusion

For the reasons described herein, Relator respectfully requests that this Court deny Defendants' Motions to Dismiss because Defendants have failed to identify a single deficiency that would mandate the dismissal of Relator's Second Amended Complaint.[10]

Respectfully submitted this 5th day of July, 2016,

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[10] In the event this Court does seek claims-specific details related to these four examples of kickback schemes, Relator respectfully requests leave to amend her complaint for the limited purpose of including claims data.

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CERTIFICATE OF SERVICE

I certify that a copy of the foregoing was filed electronically on this 5th day of July, 2016, and is available to all parties of record through the Court's electronic filing system.

s/ Jillian L. Estes
Jillian L. Estes